NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHARON MATTSON, Plaintiff, v. BRISTOL-MYERS SQUIBB CO., et al., Defendants.	:	Civil Action No. 07-908 (FLW) **OPINION**

WOLFSON, District Judge:

Pro se Plaintiff Sharon Mattson[1] ("Plaintiff" or "Ms. Mattson") brings the instant suit against Defendants, Bristol Myers-Squibb Company ("BMS"), Sanofi-Aventis U.S., L.L.C., Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo, Inc. (collectively, "Defendants"), alleging that she suffered injuries as a result of Defendants' design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and sale of their prescription drug Plavix, an anti-clotting medication. Plaintiff's Amended Complaint ("Amended Complaint") asserts various California state and common law claims against Defendants, including Failure-to-Warn, Manufacturing Defect and Negligence.[2] Before the Court is

[1] Ms. Mattson was initially represented by counsel; however, her attorney withdrew from representation on October 7, 2011. After unsuccessfully attempting to retain new counsel, Plaintiff has been proceeding pro se since that time.

[2] In her Original Complaint, Plaintiff asserted New Jersey state and common law claims against Defendants. Following

Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under California law. In response, Plaintiff submitted four handwritten letters, without any exhibits, declarations or affidavits. For the reasons that follow, Defendants' motion for summary judgment is GRANTED and all counts in the Amended Complaint are dismissed.[3]

BACKGROUND[4]

A. Plavix

Plavix is a drug that inhibits blood platelets from forming clots. The drug was initially approved by the United States Food and Drug Administration ("FDA") for use as monotherapy, i.e., taken

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two separate decisions rendered by the New Jersey Supreme Court in 2007, Plaintiff voluntarily dismissed those New Jersey claims and amended her Complaint to assert causes of action arising only under California state law. See Opinion dated December 30, 2009, pp. 2-3. Therefore, California law controls on this motion.

[3] Pending before this Court are related cases filed by other plaintiffs who were allegedly injured by ingesting Plavix, albeit their injuries may be different than those suffered by Ms. Mattson in this case. Moreover, I have been designated to handle the Plavix Multidistrict Litigation, and I am aware that there are numerous cases concerning Plavix brought against Defendants in other state and federal courts across the country. Because each plaintiff's personal circumstances differ, the Court's findings in this Opinion only represent the application of pertinent state law, i.e., California, to the facts presented in this particular case. That said, to avoid unnecessary duplication of effort in my several related cases and to conserve judicial resources, I cite to the analysis of similar legal issues in my preliminarily filed opinion in Solomon v. BMS, Civil Action No. 07-1102 (FLW), where appropriate.

[4] The following facts are undisputed unless otherwise noted.

without another drug, in patients with recent heart attack, stroke, or diagnosed peripheral vascular disease ("PVD"). See Defs. Statement, ¶ 2. Thereafter, the FDA approved Plavix for dual therapy with aspirin, which also contains antiplatelet effects, in the treatment of patients with particular types of acute coronary syndrome ("ACS").[5] Id. at ¶ 4.

Taking Plavix is not without risk. Because it functions by inhibiting the formation of blood clots, Plavix increases the risk of bleeding. In that connection, when Plavix entered the market, labeling on Plavix included certain information on that risk. The label provides:

> **PRECAUTIONS**
>
> **General**
> As with other antiplatelet agents, PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, PLAVIX should be discontinued 5 days prior to surgery.
>
> *GI Bleeding*: PLAVIX prolongs the bleeding time. In CAPRIE[6], PLAVIX was associated with a rate of

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[5] ACS is a set of clinical signs and symptoms occurring when the heart muscle does not receive enough blood because of plaque narrowing or blocking of the arteries leading to the heart. Commonly, ACS includes, inter alia, heart attacks and irregular chest pains known as unstable angina. See, e.g., Frederick G. Kushner, et al., 2009 Focused Updates: ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infraction and Guidelines on Percutaneous Coronary Intervention, 54 J. Am. C. Cardiology 2205, 2212 (2009).

[6] According to BMS, the clinical evidence for the risks of PLAVIX is derived from two double-blind trials: (i) the CAPRIE

gastrointestinal bleeding of 2.0% vs. 2.7% on aspirin. In CURE, the incidence of major gastrointestinal bleeding was 1.3% vs. 0.7% (PLAVIX + aspirin vs. placebo + aspirin, respectively). PLAVIX should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions should be used with caution in patients taking PLAVIX.

* * *

Information for Patients

Patients should be told that it may take them longer than usual to stop bleeding when they take PLAVIX, and that they should report any unusual bleeding to their physician.

* * *

ADVERSE REACTIONS

Hemorrhagic: In CAPRIE patients receiving PLAVIX, gastrointestinal hemorrhage occurred at a rate of 2.0%, and required hospitalization in 0.7%. In patients receiving aspirin, the corresponding rates were 2.7% and 1.1%, respectively. The incidence of intracranial hemorrhage was 0.4% for PLAVIX compared to 0.5% for aspirin.

In CURE, PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin (see Table 3)[7]. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal and at puncture sites. The incidence of intracranial hemorrhage (0.1%), and fatal bleeding (0.2%), was the same in both groups.

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study (Clopidogrel v. Aspirin in Patients at Risk of Ischemic Events), a comparison of PLAVIX to aspirin, and (ii) the CURE study (Clopidogrel in Unstable Angina to Prevent Recurrent Ischemic Events), a comparison of PLAVIX to placebo, both given in combination with aspirin and other standard therapy. See February 2002 Plavix Labeling, p.3. Plaintiff contests the accuracy of these clinical trials; those arguments will be further discussed in this Opinion.

[7] Table 3 of the labeling includes certain "incidence of bleeding."

See, generally, February 2002 Plavix Labeling.

B. Plaintiff's Medical History

According to her medical record, Plaintiff has a long history of heart disease and related issues.[8] In January 2005, Plaintiff went to her primary doctor, Maria T. Banico, MD, for complaints of worsening heart palpitations and accompanying chest pain. See Dr. Banico's Notes dated January 3, 2005. During this time, while Plaintiff was taking aspirin, her chest pain persisted. See Dr. Banico's Notes dated January 10, 2005 and February 28, 2005. Plaintiff was advised to see a cardiologist.

In early March 2005, Plaintiff's cardiologist diagnosed Plaintiff with unstable angina and recommended that she proceed with a coronary angiogram and stent placement. See Dr. Oh's Report dated March 7, 2005. On March 30, 2005, Dr. Gregg Hopkins performed a heart catheterization and coronary angiolasty to resolve a severe blockage in one of Plaintiff's coronary arteries. See Dr. Hopkins' Report dated April 2, 2005. A stent was also placed in Plaintiff's artery. After the surgery, Dr. Hopkins instructed Plaintiff to take aspirin as well as Plavix. Id., p. 2.

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[8] The Court notes that in response to Defendants' motion for summary judgment, Plaintiff did not submit any evidence regarding her medical history. Rather, Plaintiff, in her handwritten letters, explains her condition as a result of taking Plavix, and in a general fashion, Plaintiff complains about the use of Plavix, as well as Defendants' conduct. As such, the Court relies on Defendants' submissions of Plaintiff's medical records from her treating physician and cardiologists to piece together her medical history.

Plaintiff continued on dual therapy until December 29, 2005, when she went to the emergency room with rectal bleeding. See Discharge Summary dated January 3, 2006. While Plaintiff was admitted and closely monitored, a colonoscopy on January 3, 2006, revealed no signs of bleeding. Plaintiff was discharged on that day, and instructed to stop taking Plavix. See Id., p. 2. According to the record, Plaintiff has not taken Plavix since that time, and no additional incidences of rectal bleeding are noted.

C. Plaintiff's Amended Complaint

Due to the rectal bleeding allegedly resulting from taking Plavix, Plaintiff brings the instant suit against Defendants asserting product liability related causes of action, under California state law for failure to warn, manufacturing defect and negligence. See Am. Compl., Count I - Count III. Although these claims are characterized differently, they essentially turn on whether Defendants adequately warned that Plavix carries a risk of bleeding complications. In that regard, Defendants argue that the learned intermediary doctrine precludes Plaintiff from suing them because the doctrine excuses drug manufacturers from warning Plaintiff, individually, when these manufacturers have properly and adequately warned the prescribing physicians regarding Plavix's risks. It is this issue upon which the Court will focus.

DISCUSSION

I. Standard of Review

Summary judgment is "proper if there is no genuine issue of material fact and if, viewing the facts in the light most favorable to the non-moving party, the moving party is entitled to judgment as a matter of law." Pearson v. Component Tech. Corp., 247 F.3d 471, 482 n. 1 (3d Cir. 2001) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)); accord Fed. R. Civ. P. 56(c). For an issue to be genuine, there must be "a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party." Kaucher v. County of Bucks, 455 F.3d 418, 423 (3d Cir. 2006); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In determining whether a genuine issue of material fact exists, the court must view the facts and all reasonable inferences drawn from those facts in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Curley v. Klem, 298 F.3d 271, 276-77 (3d Cir.2002). For a fact to be material, it must have the ability to "affect the outcome of the suit under governing law." Kaucher, 455 F.3d at 423. Disputes over irrelevant or unnecessary facts will not preclude a grant of summary judgment.

Initially, the moving party has the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp., 477 U.S. at 323. Once the moving party has met this burden, the

nonmoving party must identify, by affidavits or otherwise, specific facts showing that there is a genuine issue for trial. Id.; Maidenbaum v. Bally's Park Place, Inc., 870 F.Supp. 1254, 1258 (D.N.J.1994). Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the moving party. Anderson, 477 U.S. at 256-57. "A nonmoving party may not 'rest upon mere allegations, general denials or ... vague statements...'" Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs., 982 F.2d 884, 890 (3d Cir. 1992) (quoting Quiroga v. Hasbro, Inc., 934 F.2d 497, 500 (3d Cir. 1991)). Moreover, the non-moving party must present "more than a scintilla of evidence showing that there is a genuine issue for trial." Woloszyn v. County of Lawrence, 396 F.3d 314, 319 (3d Cir. 2005). Indeed, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. Celotex Corp., 477 U.S. at 322.

Moreover, in deciding the merits of a party's motion for summary judgment, the court's role is not to evaluate the evidence and decide the truth of the matter, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249.

Credibility determinations are the province of the fact finder. Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

II. California Failure-to-Warn Claim

Because Plaintiff does not make any legal arguments or present any relevant responses to Defendants' invocation of the intermediary doctrine, the Court will undertake its own independent analysis of the law.

It is well-settled that, in California, a manufacturer of prescription drugs owes to the medical professional the duty of providing adequate warnings if it knows, or has reason to know, of any dangerous side effects of its drugs. Carlin v. The Superior Court, 13 Cal. 4th 1104, 1112-13 (1996). Under the learned intermediary doctrine, a manufacturer of a prescription drug is obliged to warn doctors – not patients – of potential side-effects associated with its pharmaceutical products. Id. at 1116; Brown v. Superior Court, 44 Cal. 3d 1049, 1061-1062 (1988); Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 65 (1973)("In the case of medical prescriptions, if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed (internal quotations omitted)).

Accordingly, "a manufacturer of prescription drugs discharges its duty to warn if it provides an adequate warning to the physician about any known or reasonably knowable dangerous side effects of a medicine, regardless of whether the warning reaches the patient." Carlin, 13 Cal. 4th at 1116-17. A plaintiff asserting causes of action for failure to warn must prove not only that no warning was provided or that the warning was inadequate, but also that the inadequacy or absence of a warning caused the plaintiff's injury. Wendell v. Johnson & Johnson, No. 09-4124, 2012 U.S. Dist. LEXIS 103986, at *23 (N.D. Cal. 2012); see Plummer v. Lederle Laboratories, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law). "[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." Motus v. Pfizer, Inc., 358 F.3d 659, 661 (9th Cir. 2004).[9]

Here, Plaintiff's failure-to-warn claim fails because the learned intermediary doctrine excuses Defendants from liability in this case. First and foremost, Plavix's warning label clearly cautions physicians and others that "PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with

[9] Although several states have adopted a heeding presumption in a failure-to-warn context, to be clear, California has not adopted such a presumption. Motus v. Pfizer, Inc., 196 F. Supp. 2d 984, 995-95 (C.D. Cal. 2001); Dimond v. Caterpillar Tractor Co. 65 Cal. App.3d 173, 185, n. 8 (1976); Johnson v. Johnson & Johnson, No. B211123, 2010 Cal. App. Unpub. LEXIS 8274, at *37 (2nd App. Dist. Oct. 20, 2010).

aspirin. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal . . . sites." See February 2002 Plavix Labeling. In addition, the label references a table, taken from the CURE study, which publishes statistics regarding incidence of bleeding when taking Plavix and aspirin together compared to taking aspirin with a placebo (e.g., Major bleeding: 3.7% v. 2.7%). See Id., Table 3. It is, then, Plaintiff's burden to demonstrate that the treating physician would not have used or prescribed the product but for the inadequate warning. Having reviewed Plaintiff's cardiologist's testimony, the Court finds a stronger warning would have not have changed the physician's decision to prescribe Plavix to Plaintiff.

As the interventionalist, Dr. Hopkins testified that Plaintiff was placed on Plavix and aspirin because her medical condition was serious after her surgery, and that the likelihood of Plaintiff having heart-related complications was high. See Dr. Hopkins' Dep., T57:13-59:6. In that respect, Dr. Hopkins explained that based upon Plaintiff's medical situation, there was a strong likelihood of blood clotting with the placement of stents in Plaintiff's arteries. Id., T64:19-65:4. The doctor determined that placing Plaintiff on dual therapy with Plavix and aspirin was not only the standard of care at the time, but it was in her best interest. Id., T65:5-14.

Indeed, Dr. Hopkins was aware that there were risks associated with this type of treatment. Importantly, Dr. Hopkins acknowledged that dual therapy could cause serious risk of bleeding in patients. He explained: "The biggest risk is bleeding . . . . [I]t can cause bleeding from any location, typically patients who are taking aspirin and Plavix will have increased bruising, or they'll bruise easily. It takes longer for a cut or a scratch to stop oozing. They can also develop nosebleeds. They can have gastrointestinal bleeding . . . It can also be lower gastrointestinal bleeding."[10] Id., T63:1-10. However, the cardiologist insisted that despite the risks, it was important that these drugs were prescribed to Plaintiff to prevent further complications. Id., T65:1-4. In fact, Dr. Hopkins explained that the standard of medical practice today, let alone in 2005, is to provide the combination of Plavix and aspirin for patients like Plaintiff, and that he would continue to prescribe Plavix to patients like Plaintiff. Id., T66:3-67:18. Furthermore, Dr. Hopkins testified that he did not solely rely on Plavix's warning labels to apprise himself of the risks and benefits of the drug. Id. T34:15-35:21. To make an informed decision, Dr. Hopkins also relied on medical journals, the Continuing Medical Education Symposia, and specific studies

[10] As it is understood by the medical community, lower gastrointestinal bleeding includes symptoms such as rectal bleeding, which was experienced by Plaintiff. See Discharge Summary dated January 3, 2006.

regarding Plavix. Id. Ultimately, the doctor reiterated that he would not have prescribed anything different to Plaintiff knowing what he knows about Plavix today. Id., T67:1-18.

It is clear from the above-testimony of Dr. Hopkins that he was aware of the serious risks of bleeding when placing Plaintiff on dual therapy with Plavix and aspirin. Indeed, Dr. Hopkins' opinions were unequivocal: because the medical benefits for Plaintiff's condition outweighed the risks, the doctor was confident that the treatment he had provided for Plaintiff was medically necessary and appropriate. There is no evidence in this case – testimonial or otherwise – to support a conclusion that a different warning would have led Plaintiff's cardiologist to alter Plaintiff's treatment. Nor is there any objective evidence in the record that would suggest that a different warning would have affected the decision of a reasonable doctor to prescribe Plavix and aspirin for Plaintiff's condition. Even more importantly, Dr. Hopkins represented that he would not have changed the prescription for Plaintiff even understanding the additional risks that have been raised by Plaintiff's allegations in this litigation.

Accordingly, because there is no causation evidence to support Plaintiff's failure-to-warn claim, it is summarily dismissed.

III. California Manufacturing Defect Claim

To prove a negligent manufacturing claim under California law, "a plaintiff must first show that the product as delivered departed

from the governing specifications." Carson v. Depuy Spine, Inc., 365 Fed. Appx. 812, 814 (9th Cir. 2010). A manufacturing defect occurs when the product "differs from the manufacturer's intended result or from other ostensibly identical units from the same product line." Barker v. Lull Engineering Co., 20 Cal. 3d 413, 429 (1978). It logically follows that if a product meets the design specifications applicable at the time of manufacture, there is no manufacturing defect. In re Coordinated Latex Glove Litigation, 99 Cal. App. 4th 594, 612-13 (2002). Here, no such evidence has been adduced by Plaintiff. Indeed, the genesis of Plaintiff's complaints about Plavix is the drug's anti-platelet properties, which allegedly caused her to suffer injuries related to massive bleeding. Those anti-clotting properties are the intended effects of Plavix, and therefore, by Plaintiff's own allegations, the nature of her claim is not premised on whether the drug deviated from the construction or specifications of Plavix. Without any evidence showing that Plavix was defectively manufactured, this claim is dismissed.

IV. Negligence Claim

Plaintiff's negligence claim is nothing more than a restatement of her defective manufacturing and failure-to-warn claims. Because the Court has found that none of her claims have merit, this claim necessarily fails.

CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is granted in its entirety. As a result, Plaintiff's Amended Complaint is dismissed.

An appropriate Order shall issue.

Dated: April 22, 2013

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge